

Docket Number JHV-009.01

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CONTROLLED RELEASE OF BIOACTIVE SUBSTANCES

the specification of which (check one)

☐ is attached hereto.
☒ was filed on July 23, 1999 as United States Application Number 09/359,593.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulation, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

☐ Yes ☐ No

☐ Yes ☐ No

(Number) (Country) (Day/Month/Year Filed)

(Number) (Country) (Day/Month/Year Filed)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States Provisional application(s) listed below.

60/093,946 July 23, 1998
 (Application Number) (Filing Date)

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Number) (Filing Date) (Status - patented, pending, abandoned)

(Application Number) (Filing Date) (Status - patented, pending, abandoned)

I hereby appoint Beth E. Arnold, Reg. No. 35,430; Charles H. Cella, Reg. No. 38,099; Kirk A. Damman, Reg. No. 42,461; Jason Gish, Reg. No. 42,581; Dana Gordon, Reg. No. 44,719; David P. Halstead, Reg. No. 44,735; Edward J. Kelly, Reg. No. 38,936; Robert A. Mazzaresse, Reg. No. 42,852; Chinh H. Pham, Reg. No. 39,329; Philip C. Swain, Reg. No. 32,376; Wolfgang E. Stutius, Reg. No. 40,256; Kingsley L. Taft, Reg. No. 43,946; Anita Varma, Reg. No. 43,221; and Matthew P. Vincent, Reg. No. 38,709 as attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all telephone calls to Kingsley L. Taft at telephone number (617) 832-1169.

Address all correspondence to: Patent Group
 Foley Hoag & Eliot LLP
 One Post Office Square
 Boston, Ma. 02109-2170

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name) Robert I. Garver Date 3/14/00
 Inventor's signature [Signature] Citizenship United States
 Residence 2116 Royal Fern Lane, Hoover, Alabama, 35244
 Post Office Address Same as above

Full name of second joint inventor, if any (given name, family name) Subramanian Kalvanasundaram Date
 Inventor's signature [Signature] Citizenship India
 Residence 355 W. Side Drive, Apt. 301, Gaithersburg, Maryland, 20878
 Post Office Address Same as above

Full name of third joint inventor, if any (given name, family name) Kam W. Leong Date
 Inventor's signature [Signature] Citizenship United States
 Residence 10242 Breconshire Road, Ellicott City, MD 21234
 Post Office Address Same as above

☐ Additional inventors are being named on separately numbered sheets attached hereto.

DECLARATION FOR PATENT APPLICATION

Docket Number JHV-009.01

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CONTROLLED RELEASE OF BIOACTIVE SUBSTANCES

the specification of which (check one)

☒ is attached hereto,
was filed on July 23, 1999 as United States Application Number 09/359,593.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulation, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

() Yes () No

() Yes () No

(Number) (Country) (Day/Month/Year Filed)

(Number) (Country) (Day/Month/Year Filed)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States Provisional application(s) listed below.

60/093,946 July 23, 1998
(Application Number) (Filing Date)

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Number) (Filing Date) (Status - patented, pending, abandoned)

(Application Number) (Filing Date) (Status - patented, pending, abandoned)

I hereby appoint Beth E. Arnold, Reg. No. 35,430; Charles H. Cella, Reg. No. 38,099; Kirk A. Damman, Reg. No. 42,461; Jason Glsh, Reg. No. 42,561; Dana Gordon, Reg. No. 44,719; David P. Halstead, Reg. No. 44,735; Edward J. Kelly, Reg. No. 38,936; Robert A. Mazzaresse, Reg. No. 42,852; Chinh H. Pham, Reg. No. 39,329; Phillip C. Swain, Reg. No. 32,376; Wolfgang E. Stutius, Reg. No. 40,258; Kingsley L. Taft, Reg. No. 43,946; Anita Varma, Reg. No. 43,221; and Matthew P. Vincent, Reg. No. 36,709 as attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all telephone calls to Kingsley L. Taft at telephone number (617) 832-1169.

Address all correspondence to: Patent Group
Foley, Hoag & Elliot LLP
One Post Office Square
Boston, Ma. 02109-2170

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name) Robert I. Garver Date _____
Inventor's signature _____ Citizenship United States
Residence 2116 Royal Fern Lane, Hoover, Alabama, 35244
Post Office Address Same as above

Full name of second joint inventor, if any (given name, family name) Subramanian Kalvanasundaram Date _____
Inventor's signature _____ Citizenship India
Residence 355 W. Side Drive, Apt. 301, Gaithersburg, Maryland, 20878
Post Office Address Same as above

Full name of third joint inventor, if any (given name, family name) Kam W. Leong Date 3/14/00
Inventor's signature Kam Leong Citizenship United States
Residence 10242 Breconshire Road, Silicon City, MD 21234
Post Office Address Same as above

() Additional inventors are being named on separately numbered sheets attached hereto.

DECLARATION FOR PATENT APPLICATION

Docket Number JHV-009.01

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CONTROLLED RELEASE OF BIOACTIVE SUBSTANCES

the specification of which (check one)

☒ is attached hereto, was filed on July 23, 1998 as United States Application Number 08/359,593.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulation, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

☐ Yes ☐ No

☐ Yes ☐ No

(Number) (Country) (Day/Month/Year Filed)

(Number) (Country) (Day/Month/Year Filed)

I hereby claim the benefit under Title 35, United States Code, § 118(a) of any United States Provisional application(s) listed below.

60/089,948 July 23, 1998
(Application Number) (Filing Date)

(Application Number) (Filing Date)

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

(Application Number) (Filing Date) (Status - patented, pending, abandoned)

(Application Number) (Filing Date) (Status - patented, pending, abandoned)

I hereby appoint Beth E. Arnold, Reg. No. 35,430; Charles H. Cella, Reg. No. 38,099; Kirk A. Damman, Reg. No. 42,451; Jason Gish, Reg. No. 42,531; Dana Gordon, Reg. No. 44,719; David P. Halstead, Reg. No. 44,715; Edward J. Kelly, Reg. No. 38,936; Robert A. Mazzarese, Reg. No. 42,852; Chinh H. Pham, Reg. No. 39,329; Philip C. Swann, Reg. No. 33,376; Wolfgang E. Studius, Reg. No. 40,256; Kingsley L. Taft, Reg. No. 43,846; Anita Vanna, Reg. No. 43,221; and Matthew P. Vincent, Reg. No. 36,708 as attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all telephone calls to Kingsley L. Taft at telephone number (617) 832-1189.

Address all correspondence to:
Patent Group
Foley, Hoag & Eliot LLP
One Post Office Square
Boston, Ma. 02109-2170

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor (given name, family name) Robert I. Carver
Inventor's signature
Residence 2116 Royal Fern Lane, Hoover, Alabama 35244
Post Office Address Same as above

Date
Citizenship United States

Full name of second joint inventor, if any (given name, family name) Subramanian Kalivasundaram
Inventor's signature
Residence 355 W. Side Drive, Apt. 301, Baltimore, Maryland 20878
Post Office Address Same as above

Date March 14, 2000
Citizenship India

Full name of third joint inventor, if any (given name, family name) Kam W. Leong
Inventor's signature
Residence 10242 Broomfield Road, Ellicott City, MD 21244
Post Office Address Same as above

Date
Citizenship United States

(1) Additional inventors are being named on separately numbered sheets attached hereto.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

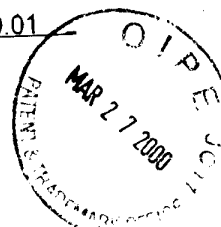
Applicants: Robert I. Garver et al.

Serial No.: 09/359,593

Filed: July 23, 1999

Title: CONTROLLED RELEASE OF BIOACTIVE SUBSTANCES

Atty Docket No.: JHV-009.01

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27)-NONPROFIT ORGANIZATION

I HEREBY DECLARE THAT I AM AN OFFICIAL EMPOWERED TO ACT ON BEHALF OF THE NONPROFIT ORGANIZATION IDENTIFIED BELOW:

Name of Nonprofit Organization: UNIVERSITY OF ALABAMA BIRMINGHAM RESEARCH FOUNDATION
Address of Nonprofit Organization: 701 SOUTH 20TH STREET, SUITE 1120-G, BIRMINGHAM, AL 35294

TYPE OF NONPROFIT ORGANIZATION:

- ☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☐ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501 (c)(3))
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA (STATE: _____) (CITATION OF STATUTE _____)
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA

I HEREBY DECLARE THAT THE NONPROFIT ORGANIZATION IDENTIFIED ABOVE QUALIFIES AS A NONPROFIT ORGANIZATION AS DEFINED IN 37 CFR 1.9(E) FOR PURPOSES OF PAYING REDUCED FEES TO THE UNITED STATES PATENT AND TRADEMARK OFFICE REGARDING THE INVENTION IDENTIFIED ABOVE.

I HEREBY DECLARE THAT RIGHTS UNDER CONTRACT OR LAW HAVE BEEN CONVEYED TO AND REMAIN WITH THE NONPROFIT ORGANIZATION REGARDING THE ABOVE-IDENTIFIED INVENTION.

IF THE RIGHTS HELD BY THE NONPROFIT ORGANIZATION ARE NOT EXCLUSIVE, EACH INDIVIDUAL, CONCERN OR ORGANIZATION HAVING RIGHTS IN THE INVENTION IS LISTED BELOW* AND NO RIGHTS TO THE INVENTION ARE HELD BY ANY PERSON, OTHER THAN THE INVENTOR WHO WOULD NOT QUALIFY AS AN INDEPENDENT INVENTOR UNDER 37 CFR 1.9(C) IF THAT PERSON MADE THE INVENTION, OR BY ANY CONCERN WHICH WOULD NOT QUALIFY AS A SMALL BUSINESS CONCERN UNDER 37 CFR 1.9(D) OR A NONPROFIT ORGANIZATION UNDER 37 CFR 1.9(E).

*NOTE: SEPARATE VERIFIED STATEMENTS ARE REQUIRED FROM EACH NAMED PERSON, CONCERN OR ORGANIZATION HAVING RIGHTS TO THE INVENTION AVERRING TO THEIR STATUS AS SMALL ENTITIES (37 CFR 1.27)

NAME Johns Hopkins University School of MedicineADDRESS 111 Market Place, Suite 906, Baltimore, MD 21202☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☒ NONPROFIT ORGANIZATION

I ACKNOWLEDGE THE DUTY TO FILE, IN THIS APPLICATION OR PATENT, NOTIFICATION OF ANY CHANGE IN STATUS RESULTING IN LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS PRIOR TO PAYING, OR AT THE TIME OF PAYING, THE EARLIEST OF THE ISSUE FEE OR ANY MAINTENANCE FEE DUE AFTER THE DATE ON WHICH STATUS AS A SMALL ENTITY IS NO LONGER APPROPRIATE. (37 CFR 1.28(b))

I HEREBY DECLARE THAT ALL STATEMENTS MADE HEREIN OF MY OWN KNOWLEDGE ARE TRUE AND THAT ALL STATEMENTS MADE ON INFORMATION AND BELIEF ARE BELIEVED TO BE TRUE; AND FURTHER THAT THESE STATEMENTS WERE MADE WITH THE KNOWLEDGE THAT WILLFUL FALSE STATEMENTS AND THE LIKE SO MADE ARE PUNISHABLE BY FINE OR IMPRISONMENT, OR BOTH, UNDER SECTION 1001 OF TITLE 18 OF THE UNITED STATES CODE, AND THAT SUCH WILLFUL FALSE STATEMENTS MAY JEOPARDIZE THE VALIDITY OF THE APPLICATION, ANY PATENT ISSUING THEREON, OR ANY PATENT TO WHICH THIS VERIFIED STATEMENT IS DIRECTED.

NAME/TITLE OF PERSON SIGNING: David L. Day, UABRF DirectorADDRESS OF PERSON SIGNING: UNIVERSITY OF ALABAMA BIRMINGHAM RESEARCH FOUNDATION, 701 SOUTH 20TH STREET, SUITE 1120-G, BIRMINGHAM, ALABAMA 35294SIGNATURE David L. DayDATE 3/15/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

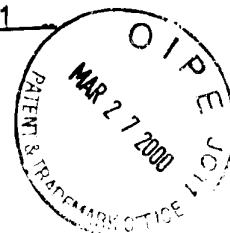
Applicants: Robert I. Garver et al.

Serial No.: 09/359,593

Filed: July 23, 1999

Title: CONTROLLED RELEASE OF BIOACTIVE SUBSTANCES

Atty Docket No.: JHV-009.01

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) & 1.27)-NONPROFIT ORGANIZATION

I HEREBY DECLARE THAT I AM AN OFFICIAL EMPOWERED TO ACT ON BEHALF OF THE NONPROFIT ORGANIZATION IDENTIFIED BELOW:

Name of Nonprofit Organization: JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINEAddress of Nonprofit Organization: 111 MARKET PLACE, SUITE 906, BALTIMORE, MD 21202

TYPE OF NONPROFIT ORGANIZATION:

- ☒ UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
☒ TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501 (c)(3))
☐ NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA (STATE: _____) (CITATION OF STATUTE _____)
☐ WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 U.S.C. 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
☐ WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA

I HEREBY DECLARE THAT THE NONPROFIT ORGANIZATION IDENTIFIED ABOVE QUALIFIES AS A NONPROFIT ORGANIZATION AS DEFINED IN 37 CFR 1.9(e) FOR PURPOSES OF PAYING REDUCED FEES TO THE UNITED STATES PATENT AND TRADEMARK OFFICE REGARDING THE INVENTION IDENTIFIED ABOVE.

I HEREBY DECLARE THAT RIGHTS UNDER CONTRACT OR LAW HAVE BEEN CONVEYED TO AND REMAIN WITH THE NONPROFIT ORGANIZATION REGARDING THE ABOVE-IDENTIFIED INVENTION.

IF THE RIGHTS HELD BY THE NONPROFIT ORGANIZATION ARE NOT EXCLUSIVE, EACH INDIVIDUAL, CONCERN OR ORGANIZATION HAVING RIGHTS IN THE INVENTION IS LISTED BELOW AND NO RIGHTS TO THE INVENTION ARE HELD BY ANY PERSON, OTHER THAN THE INVENTOR WHO WOULD NOT QUALIFY AS AN INDEPENDENT INVENTOR UNDER 37 CFR 1.9(C) IF THAT PERSON MADE THE INVENTION, OR BY ANY CONCERN WHICH WOULD NOT QUALIFY AS A SMALL BUSINESS CONCERN UNDER 37 CFR 1.9(D) OR A NONPROFIT ORGANIZATION UNDER 37 CFR 1.9(E).

*NOTE: SEPARATE VERIFIED STATEMENTS ARE REQUIRED FROM EACH NAMED PERSON, CONCERN OR ORGANIZATION HAVING RIGHTS TO THE INVENTION AVERRING TO THEIR STATUS AS SMALL ENTITIES (37 CFR 1.27)

NAME University of Alabama Birmingham Research FoundationADDRESS 701 South 20th Street, Suite 1120-G, Birmingham, Alabama 35294☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☒ NONPROFIT ORGANIZATION

I ACKNOWLEDGE THE DUTY TO FILE, IN THIS APPLICATION OR PATENT, NOTIFICATION OF ANY CHANGE IN STATUS RESULTING IN LOSS OF ENTITLEMENT TO SMALL ENTITY STATUS PRIOR TO PAYING, OR AT THE TIME OF PAYING, THE EARLIEST OF THE ISSUE FEE OR ANY MAINTENANCE FEE DUE AFTER THE DATE ON WHICH STATUS AS A SMALL ENTITY IS NO LONGER APPROPRIATE. (37 CFR 1.28(b))

I HEREBY DECLARE THAT ALL STATEMENTS MADE HEREIN OF MY OWN KNOWLEDGE ARE TRUE AND THAT ALL STATEMENTS MADE ON INFORMATION AND BELIEF ARE BELIEVED TO BE TRUE; AND FURTHER THAT THESE STATEMENTS WERE MADE WITH THE KNOWLEDGE THAT WILLFUL FALSE STATEMENTS AND THE LIKE SO MADE ARE PUNISHABLE BY FINE OR IMPRISONMENT, OR BOTH, UNDER SECTION 1001 OF TITLE 18 OF THE UNITED STATES CODE, AND THAT SUCH WILLFUL FALSE STATEMENTS MAY JEOPARDIZE THE VALIDITY OF THE APPLICATION, ANY PATENT ISSUING THEREON, OR ANY PATENT TO WHICH THIS VERIFIED STATEMENT IS DIRECTED.

NAME/TITLE OF PERSON SIGNING: NINA OSSANNA, PH.D., ASSOCIATE DIRECTORADDRESS OF PERSON SIGNING: OFFICE OF TECHNOLOGY LICENSING, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, 111 MARKET PLACE, SUITE 906, BALTIMORE, MD 21202SIGNATURE DATE 3/15/00